

Attorney Docket No. 4409.214-US
Filed: January 30, 2001
Title: Protracted Polypeptides

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AUG 14 2007

Application No. 09/772,607
Inventors: Jonassen et al.
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REMARKS/ARGUMENTS

Following entry of this Amendment, claims 48-59 are pending.

Examiner has withdrawn the previous rejection of claims 48 and 49 under 35 U.S.C. 102(b) as being anticipated by Habener (U.S. Patent 5,118,666) in view of applicant's response at pages 7-8 in the amendment filed December 21, 2006.

Applicants gratefully acknowledge the courtesy extended by Primary Patent Examiner Kam and Supervisory Patent Examiner Bragdon to the undersigned during a telephone interview on August 9, 2007

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION OF THE CLAIMS

The Examiner has maintained the provisional rejection under the judicially created doctrine of obvious-type double patenting of claims 48-55 and 57-59 as being unpatentable over claims 1-3, 5-7 and 15 of copending application 09/757,788 based on the amendment filed December 21, 2006.

In reply, the Examiners indicated in the August 9, 2007 interview that they would reconsider this rejection if the claims of copending 09/757,788 were amended to recite that the claimed formulations contained additional components.

By Amendment filed August 13, 2007 in copending application 09/757,788, independent Applicants amended claims 1 and 27 to recite that the claimed formulations include diphosphatidylcholine in addition to a GLP-1 compound. Claim 1 of copending application 09/757,788 is reproduced below:

"A liquid formulation suitable for pulmonary administration to a subject, said formulation comprising diphosphatidyl choline (DPPC) and a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um."

Applicants therefore respectfully request that this rejection be withdrawn since the GLP-1 derivatives of the present claims are not an obvious variation of a liquid formulation suitable for

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pulmonary administration comprising diphosphatidyl choline (DPPC) and a GLP-1 compound as presently claimed in copending application 09/757,788.

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REJECTIONS UNDER 35 U.S.C. 103(a)

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The Examiner has rejected claims 48 and 49 as being unpatentable over Habener (U.S. Patent 5,118,666, publication date: June 2, 1992). In setting forth this rejection, the Examiner asserts that while the GLP-1 derivative with a C₁-C₆ group attached to its C-terminus is prepared in Habener, "it is obvious that alkyl group greater than C₆ can be used to attach to the C-terminus amino acid of GLP-1 peptide" (page 6 of Office Action).

In the August 9, 2007 interview, it was agreed that the Examiner had failed to provide evidence or reasoning sufficient to support the present obviousness rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

In sum, in view of the above amendments and remarks, Applicants submit that the present application is in condition for allowance and early and favorable consideration to this effect is respectfully solicited.

Respectfully submitted,

Date: August 14, 2007

/Richard W. Bork, Reg. No. 36,459/
Richard W. Bork, Reg. No. 36,459
Novo Nordisk, Inc.
Customer Number 23650
(609) 987-5800

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